

### **REMARKS**

Claims 130-152 are pending. Claims 153-160 are new. Support for claims 153-160 is found, for example, in claims 130, 131 and 146, Formula XVII on page 40, page 53, line 11 of the specification, and in the subembodiments found on page 44 of the specification. New claims 153-156 are also supported by the third preferred embodiment on pages 24-25 of U.S. Provisional Application No. 60/206,585 (“the ‘585 application”), to which this application claims priority, and which is incorporated by reference on page 12 of the specification. Further support for new claims 154-160 is found on pages 21 and 48 of the ‘585 application, wherein prodrugs including acylation products are provided, and page 47 of the ‘585 application, wherein “lower acyl” is defined. No new matter is added by these amendments.

Applicants respectfully request reconsideration of the pending rejections based on the following comments.

#### **Obviousness-Type Double Patenting Rejections**

##### **A. U.S. Patent Nos. 6,812,219; 7,148,206 and 7,105,493.**

Claims 130-131 and 137-149 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-32 of U.S. Patent No. 6,812,219 (“the ‘219 patent”); claims 130, 132-146 and 150-152 are rejected as allegedly being unpatentable over claims 1-42 of U.S. Patent No. 7,148,206 (“the ‘206 patent”); and claims 130-152 are rejected as allegedly being unpatentable over claims 1-18 of U.S. Patent No. 7,105,493 (“the ‘493 patent”). Specifically, the Examiner alleges the instant claims are not patentably distinct from the claims of the ‘219, ‘206 and ‘493 patents because each set of claims is “drawn to methods of treating viruses from the Flaviviridae virus family....” (Office Action, pages 6-7). Applicants respectfully disagree.

An obviousness-type double patenting rejection is appropriate only when the claims at issue are not “patentably distinct” from the claims of a commonly owned earlier patent. *See Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). A claim is not patentably distinct from an earlier patent claim if the later claim is “obvious over, or anticipated by, the earlier claim.” *Id.* at 968.

The instant claims recite, *inter alia*, methods of treating hepatitis C virus infections. As pointed out in Applicants’ previous response, the ‘219, ‘206 and ‘493 patents disclose methods of treating flavivirus or pestivirus infections, while the instant claims recite methods

of treating hepatitis C virus infections. The mere fact that the viruses recited in the claims of '219, '206 and '493 patents belong to the same family as the virus of the instant claims does not change the fact that they are distinct viruses. Indeed, the specification of each of the patents cited by the Examiner discloses that hepatitis C virus belongs to its *own genus*, hepacivirus, which is distinct from the flavivirus and pestivirus genres. (Column 12, lines 6-9). Thus, the instant claims are directed to an *entirely different invention* than the claims of the '219, '206 and '493 patents—the treatment of hepatitis C virus infections, not flavivirus or pestivirus infections. The policy behind a double patenting rejection—the prevention of an unjustified extension of the term of a patent—does not support the Examiner's rejection in this case. *See In re Kaplan*, 789 F.2d 1574, 1579 (Fed. Cir. 1986) (“the basis for...obviousness-type double patenting rejections is timewise extension of the patent right”). Allowance of the instant claims, directed to hepatitis C virus infections, would not result in the extension of the terms of the '219, '206 and '493 patents, each of which covers only flavivirus and pestivirus infections. Therefore, Applicants respectfully request that the double patenting rejection be withdrawn.

**B. Provisional Obviousness-Type Double Patenting Rejections over U.S. Patent Application Nos. 10/609,298; 11/005,440; 11/005,443; 11/005,444; 11/005,446 and 11/005,466.**

Claims 130-152 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the claims of U.S. Patent Application Nos. 10/609,298; 11/005,440; 11/005,443; 11/005,444; 11/005,446 and 11/005,466.

If provisional obviousness-type double patenting rejections are the only rejections remaining in an earlier filed pending application, the Examiner should withdraw those rejections and permit the earlier-filed application to issue as a patent without a Terminal Disclaimer. Manual of Patent Examination Procedure § 804, subsection I.B.

The filing date of the instant application is June 20, 2003. The filing date of U.S. Patent Application No. 10/609,298 is June 27, 2003. The filing date of each of U.S. Patent Application Nos. 11/005,440; 11/005,443; 11/005,444; 11/005,446 and 11/005,466 is December 6, 2004. Therefore, because the instant application is the earlier-filed application, and only provisional obviousness-type double patenting rejections remain, Applicants respectfully request that the Examiner withdraw the rejections and allow the instant application to issue as a patent without a Terminal Disclaimer.

**CONCLUSION**

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Please apply fees for a Request for Continued Examination (\$810.00) and any other charges, or any credits, to Jones Day Deposit Account No. 503013 (ref. no. 417451-999043).

If the Examiner believes it would be useful to advance prosecution, the Examiner is invited to telephone the undersigned at (858) 314-1200.

Respectfully submitted,

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